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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,146	12/16/2004	Albert Schaap	GRT/4662-368	9953
23117 7590 08/07/2007 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER MAASHO, KERIMA K	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 08/07/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/518,146	SCHAAP ET AL.	
	Examiner	Art Unit	
	Kerima Maasho	1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4,11 and 14-35 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,4 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 14-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/25/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

***Detailed action***

Applicant's election with traverse of group II drawn to microbial oil in the reply filed on 06/27/2007 is acknowledged. The traversal is on the ground(s) that the invention groups are closely related as to form a single general inventive concept and do not require separate search. The method of pasteurizing microbial cells or organisms may or may not result in the microbial oil as claimed. The method as claimed does not refer to a process for obtaining microbial oil thus, the requirement is still deemed proper and is therefore maintained.

Claims 1, 2, 4, and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 14-35 are pending and are under consideration for further examination.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 14-34 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Applicants claim "a microbial oil comprising at least ...." the microbial oil is not recited as isolated or in some

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other fashion extracted from the microbe, as claimed the microbe and any oil it possesses are a product of nature as microbial oils are naturally produced by microorganisms during their life span. The recitation of the limitation "isolated or extracted microbial oil", or if the reference is a composition "a composition of microbial oil" would be remedial.

***Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 29-35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 provides a process of using microbial oil, "the process comprising: subjecting the microbial oil to one or more steps...", but the claim does not set forth any steps involved in the method/process except for merely stating that it involves subjecting the microbial oil to one or more refining steps and is therefore unclear what process applicant is intending to encompass. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The

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claims as they stand are incomplete and fail to provide adequate steps to allow for one to identify what is being claimed.

Claims 30-35 are also indefinite insofar as they depend directly or indirectly from claim 29.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-25 refer to a microbial oil, claims 26-28 refer to a foodstuff comprising the microbial oil, and claims 29-31 refer to a process of using the microbial oil for refinement, and adding to food stuff. Claim 35 refers to a process of making the microbial oil by extracting from microbial cells or organisms.

3. Claims 14-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Bijl et al (WO 97/37032 filed in the IDS) in light of Beuderker et al (WO 99/65327).

Bijl et al teach a microbial polyunsaturated fatty acid containing oil with a high triglyceride content and a high oxidative stability which is derived from a bacterial biomass derived from a pasteurized fermentation broth. Bijl et al teach such derived microbial oil comprising of arachidonic acid with a triglyceride

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content of greater than 90%, that has anisidine value of at least 5 (pages 4-5).

The peroxide value of less than 12 and less than 1.5 were shown in the crude and refined oil (see example 23 pages 49 and 50). Bijl et al also teach that this microbial oil can be produced by fungus that belongs to the *Mortierella* species (e.g. *M. alpine*) and that solvents can be used to extract lipid from the bacterial biomass (see background and page 14). Furthermore they teach that the crude form of the extracted lipid is subjected to several refining steps to provide refined oil. Bijl et al also teach the microbial oil can advantageously be used in foods, food stuffs or food compositions or serve as a nutritional supplement, for humans as well as for animals and in particular for inclusion in infant formula (pages 4 and 9-10). Bijl et al teach a process of making the microbial oil complete with the extraction of the microbial oil from the microbial cells or organisms. The source of oil obtained from Bijl would inherently be that of at least 10% arachidonic acid.

Beudeker et al is cited merely to show that a high content of microbial arachidonic acid typically 10-40% can be obtained for example from single cell source (e.g. *M. alpina*) by using the exact same fermentation and extraction method as used in Bijl et al (p 3 - p 6).

Therefore, Bijl et al anticipates all the limitations of claims 14-35 of the present invention.

### ***Conclusion***

Claims 14-35 are rejected as explained above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kerima Maasho whose telephone number is 571-270-3055. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Graser/

Primary Examiner, Art Unit 1645

*Kerima K Maasho*  
Patent Examiner  
ART UNIT 1645